Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576-J
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	
PERSON INTERVIEWED:	Sarah Bennett, CMS
PLACE OF INTERVIEW:	Webex
DATE OF INTERVIEW:	10/29/2021
TIME OF INTERVIEW:	1100 PST
INTERVIEWED BY:	SAIC George Scavdis
OTHER PERSONS PRESENT:	See below

On October 29, 2021, the case agent telephonically interviewed Sarah Bennet, Acting Branch Manager, Center for Medicare and Medicaid Services (CMS) regarding CMS' 2015 inspection of Theranos, Inc. (Theranos). Also present during the interview were the following: Lindsay Turner, Attorney, Department of Health and Human Services, Office of the General Counsel; Assistant United States Attorney (AUSA) Robert Leach, United States Attorney's Office for the Northern District of California (USAO/NDC); AUSA John Bostic, USAO/NDC; and AUSA Jeffrey Schenk, USAO/NDC.

Ms. Bennett is the Acting Branch Manager for Policy B and the Technical Director in the division. She manages a number of employees and is responsible for one half of the team that is charged with developing policy for CLIA (Clinical Laboratory Improvement Act). As the Technical Director, she is a point of contact within the division, and she is a liaison with management for the policy technical staff. Anytime they need technical advice or consultation, they come to her so they can discuss and decide what is applicable to CLIA.

Ms. Bennett explained that if a complaint comes into CMS about a laboratory around the regular scheduled time of that laboratory's survey, the two will be combined. This is what happened with Theranos. CMS received two complaints and they decided to do the recertification survey at the same time as the complaint survey. The "New York" complaint had to do with proficiency testing (PT)-specifically that Theranos was performing PT both on their proprietary device and on traditional devices, yet they were only submitting PT testing data on the traditional devices when they're primary method of testing was on the proprietary devices. The other complaint CMS received came from Erica Cheung.

At Elizabeth Holmes' first meeting with CMS, Ms. Holmes said Theranos was not live yet regarding testing on their proprietary device, and that they were just in the planning stages. Theranos only wanted a CLIA certificate for their California laboratory, and CMS said they must have one in every Walgreens store that was going to have a Theranos proprietary device in it.

Ms. Bennet explained that Theranos' PT reports only included regulated analytes. They did not contain alternative assessment proficiency (AAP) testing data in them because AAP is not part of the CLIA regulations. The PT reports she looked at during the Theranos inspection didn't have anything to do with laboratory developed test (LDTs). She wouldn't have been able to tell from a PT report if Theranos had modified a test; the report only tells you the test and the score. CMS understood before their 2015 Theranos inspection that FDA had previously inspected Theranos, but Ms. Bennett didn't know the results of that

inspection. The CMS inspection of Theranos was originally attempted to be scheduled for the end of August 2015, and it got pushed back to September 2015 because Theranos didn't have the appropriate staff.

Dr. Young told CMS during the audit of Theranos' Arizona laboratory that Theranos did not do any testing on their proprietary devices at that laboratory.

Ms. Bennett had no interaction with Sunil Dhawan during the 2015 CMS survey. He came at one point during the survey for an hour and "didn't say a word." Ms. Bennett doesn't know the name Lynette Sawyer. She explained that CLIA does not allow for co-lab directors. Sunny Balwani was the "in charge" person when they were in the room during the Theranos survey, and Heather King was also very "vocal."

Following its survey of Theranos CMS proposed revocation, which would have affected Ms. Holmes as the owner of the laboratory. Ms. Bennett explained that sanctions are taken against a laboratory, but in the case of revocation there is an additional action which prohibits the laboratory director and the owner/operator from owning or operating a laboratory for two years. Section 493.2 of the CLIA regulations defines what an "owner" and what an "operator" are. There are circumstances where both the owner and the operator have responsibility for what goes on in the lab. Section 493.1840 of the CLIA regulations specifies the two-year prohibition that can be imposed on a laboratory owner.

AUSA Leach asked Ms. Bennett about trial exhibit 4533. Mr. Balwani gave this list to Ms. Bennett in response to her request for the start and end dates of Theranos testing on their proprietary device. She asked for this because Mr. Balwani said they no longer tested patients on it. She used this list to ask for the validations of the tests, to check testing personnel qualifications, and to ask for quality control (QC) information in random intervals. She did a random sampling of 4 or 5 tests on the list.

The Theranos employees that Ms. Bennett interacted with the most during the September 2015 portion of the survey were "Gurbir," "Hoda," and "Langly." CMS surveyor Gary Yamamoto handled the pre-analytic portion of the survey and some of the microbiology. Ms. Bennett handled the coagulation portion and the PT documentation. She reviewed the AAP reports for the Edison. What she cited to in the CMS 2567 was that Theranos had not followed their procedure for AAP or done AAP at the intervals they were required to by the regulations or their own procedure. The Dtag in the CMS 2567 that address that citation is D5217 on pages 67 and 68.

CMS completed the survey of Theranos in November 2015. During the November portion of the survey, Ms. Bennett spent a lot of time on Theranos personnel and on getting the information about the Edison, specifically the validations and the QC reports. She found that they did not follow their own procedures on their validation reports, yet they were signed off on and they did the patient testing anyway. As a result, there's no way Theranos could know that their tests on the Edison were accurate and reliable. During the November portion of the survey, she was dealing with the same people she was in September, but this time Ms. Holmes was also there. At the end of November, CMS told Ms. Holmes they were considering "Immediate Jeopardy." It's the CMS surveyor who makes the call of "Standard Level" vs. "Condition Level" deficiency, as well as "Immediate Jeopardy." "Immediate Jeopardy" is saved for the most egregious cases. An "Immediate Jeopardy" designation for a lab is rare. On the last day of the survey, Ms. Holmes and Mr. Balwani were negotiating with Ms. Bennett and CMS for them not to cite certain things in the CMS 2567. Ms. Holmes had a wavering voice, and her eyes were misty and teary at the time.

Ms. Holmes requested a meeting with Kate Goodrich from CMS in or around April 2016. Ms. Goodrich was the director of CCSQ (Center for Clinical Standards and Quality) in April 2016, and Theranos came in to plead their case again and to assure CMS they would come into compliance. Ms. Bennett was just a listener at that meeting.

SUBMITTED: Electronically submitted by GEORGESCAVDIS

GEORGE SCAVDIS, SPECIAL AGENT IN CHARGE DATE: 10/29/2021

APPROVED: _____

DATE:

DISTRIBUTION: Orig: MWM w/attachment
cc: Prosecution w/attachment

ATTACHMENTS: 1 - Trial Exhibit 4533

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September 23, 2015

To Whom It May Concern:

You requested a current list of the platforms on which all of our tests are running as of September 22, 2015. We are providing that information to you under separate cover. Additionally, the following is the list of the Laboratory Developed Tests (LDTs) that Theranos tested on Theranos device, also called Theranos Sample Processing Units (TSPUs), along with the time periods when those tests were run. Theranos recently received FDA clearance for its Theranos System – including the device, the Theranos Sample Collection Device (including the nanotainers) and other components of the system - , and plans to bring these units live again in the lab as 510k-cleared analyzers, rather than LDTs, once additional clearances are obtained.

As we explained in person, Theranos changes the platforms on which it runs tests from time to time. The decision to move testing off of TSPUs and onto other platforms in this case was a business decision to transition to the manufacturing quality systems to QSR compliance under FDA guidelines and does not reflect on the reliability or accuracy of any platform.

Theranos has never commercially distributed a TSPU.

Test	Initial	End
Vit D	11/6/2013	3/10/2015
TSH	11/7/2013	2/4/2015
FT4	11/11/2013	2/4/2015
TPSA	11/11/2013	6/25/2015
TT3	2/12/2014	2/4/2015
TT4	2/12/2014	2/4/2015
TST	3/19/2014	3/10/2015
HCG	5/9/2014	1/19/2015
SHBG	7/28/2014	6/25/2015
VB12	8/12/2014	3/6/2015
Estradiol	9/25/2014	12/18/2014
Prolactin	9/25/2014	12/18/2014